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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,450	12/12/2003	Shintaro Washizu	Q78911	2318

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EXAMINER

DETSCHER, MARISSA

ART UNIT	PAPER NUMBER
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2877

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/733,450	WASHIZU ET AL.	
	Examiner	Art Unit	
	Marissa J. Detschel	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-53 is/are rejected.
- 7) ☒ Claim(s) 7, 27, 28 and 53 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/15/04, 8/15/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 2002-362706, filed on December 13, 2002.

Information Disclosure Statement

The information disclosure statements filed on March 25, 2004, and August 15, 2005, have been fully considered by the examiner.

Drawings

The drawings are objected to because Applicant fails to discriminate amongst the three lines in Figure 18. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the

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examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The disclosure is objected to because of the following informalities: The specification fails to disclose reference characters 2 and 10c in figures 13-15. The disclosure of these reference characters is pertinent in understanding applicant's claimed disclosure.

Appropriate correction is required.

Claim Objections

Claims 7, 27, 28, and 53 are objected to because of the following informalities:

As to claim 7, the phrase "radiates interference light at least one" should be "radiates interference light as at least one" in line 2 of this claim.

As to claims 27 and 28, the limitation "the target detection part" appears in the second line of these claims. Based on claim 26, which claims 27 and 28 are dependent from, this limitation should read "the target interaction part" because claim 26 recites "a target interaction part which can interact with the detection target." Claims 27 and 28 as presented claims "the target detection part can interact with the detection target." Based on claim 26, it is the target interaction part that interacts with the detection target, and not a target detection part.

As to claim 53, this claim should read "the optical interference unit is a target detection substrate formed from a film-like material on a substrate which can interact with a detection target, interfere with irradiate light and radiate it as interference light, and can change the wavelength of the interference light after interaction with the detection target" in order for the claim to be grammatically correct.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7-9, 12-21, 34-36, 38-46, and 51-53 rejected under 35 U.S.C. 102(b) as being anticipated by Kawaguchi, et al. (Kawaguchi, T., Shiro, T., and Iwata, K., "A Device for Visual Detection of Antigens and Antibodies by Means of Light Interference." *Thin Solid Films*. Vol. 91, pp. 369-381 (1990)).

Regarding claim 1, Kawaguchi discloses an apparatus comprising
an optical irradiation unit with irradiates light (page 374, section 3.4, lines 2-3),
an optical interference unit which can interact with a detection target, interferes with the light irradiated from the optical irradiation unit and radiates it as interference light, and is able to vary the wavelength of the interference light after interaction with the detection target (page 374, section 3.4, lines 3-6), and

a wavelength change detecting unit placed in the path of the interference light which detects the wavelength variation of the interference light radiated by the optical interference unit (page 371, section 2.4, lines 14-16 and figure 5).

In regards to claim 2, the wavelength change detecting unit of Kawaguchi transmits light of a specific wavelength and can detect that light of the specific wavelength has been passed through (page 371, section 2.4, lines 14-16 and figure 5).

In regards to claim 3, Kawaguchi's apparatus comprises an interference filter, and an optical detection sensor (page 371, section 2.4, lines 14-16) which can detect light which has passed through the interference filter (page 371, section 2.4, lines 14-16 and figure 5). The model used of the film-like material of a light-filtering layer coating a light-reflecting substrate exemplifies an interference filter (page 370, section 2.1.2, lines 1-3).

In regards to claim 7 and 36, the optical interference unit of Kawaguchi radiates interference light as at least one selected from a reflected light and a transmitted light. Kawaguchi uses reflected light (page 374, section 3.4, lines 2-5)

Regarding claim 8, the optical interference unit of Kawaguchi comprises a film-like material (figure 3, layer 2).

In regards to claim 9, the optical interference unit of Kawaguchi further comprises a substrate (3), and the film-like material (light-interfering layer 2) is provided on the substrate (figure 3).

Regarding claims 21 and 46, the thickness of the film-like material is 100nm (page 379, section 3.6, lines 2-6).

Regarding claims 12 and 38, the substrate of Kawaguchi is formed from at least one of semiconductor, ceramics, metal, glass, and plastics. Kawaguchi's substrate is formed from either a nickel-plated iron plate called Ferrottype or silicon (page 370, section 2.1.2, lines 1-2).

In regards to claims 13 and 39, the substrate of Kawaguchi comprises on a surface thereof an identical refractive index film (immobilized antibody layer 1) having

substantially the same refractive index to a refractive index of the film-like material (2) (page 374, section 3.4, lines 5-7).

In regards to claim 14 and 40, the substrate of Kawaguchi comprises on a surface thereof a different refractive index film (1) having a different refractive index to a refractive index of the film-like material (2) (page 376, section 3.5, paragraph 3, lines 2-6).

Regarding claims 15 and 41, the refractive index of Kawaguchi's different refractive index film (1) is different from a refractive index of the substrate (3) (page 376, section 3.5, paragraph 3, lines 2-6).

Regarding claims 16 and 42, Kawaguchi's apparatus comprises a plurality of different refractive index films, refractive indices of the plurality of different refractive index films being mutually different (page 376, section 3.5, paragraph 3, lines 5-6).

In regards to claims 17, 43, and 45, the different refractive index film of Kawaguchi's device is a dielectric film (page 375, section 3.4, lines 9-12). Proteins are a dielectric substance.

In regards to claims 18 and 44, the substrate of Kawaguchi's apparatus is an interference filter. The model used of the film-like material of a light-filtering layer coating a light-reflecting substrate exemplifies an interference filter (page 370, section 2.1.2, lines 1-3).

Regarding claim 19, at least one film (1) is further formed on the surface of the film-like material (2) of Kawaguchi's substrate (3) (Figure 5).

In regards to claim 20, the film (1) of Kawaguchi's device can have a refractive index substantially the same to the refractive index of the substrate (3) surface in contact with the film-like material. (page 376, section 3.5, paragraph 3, lines 1-6) This can be accomplished by using the silicon wafer disclosed by Kawaguchi (page 370, section 2.1.2, lines 1-2) instead of the Ferrottype wafer. The refractive index of a silicon wafer is about 1.5.

In regards to claim 34, Kawaguchi's apparatus includes a substrate comprising:

a film-like material (2); and

a substrate (3), wherein the film-like material (2) is provided on the substrate, and the substrate can interact with a detection target, interfere with irradiated light and radiate it as interference light, and change the wavelength of the interference light after interacting with the detection target. (figure 5 and page 374, section 3.4, lines 3-6 and page 371, section 2.4, lines 14-16)

Regarding claim 35, the interaction of Kawaguchi's substrate is at least one selected from physical adsorption and chemical adsorption. The antigen-antibody reaction of the device is an example of a chemical adsorption process which creates interference color changes (page 375, section 3.4, lines 8-11).

In regards to claim 51, Kawaguchi discloses a method of:

irradiating light to an optical interference unit which can interact with a detection target, and radiate the light as interference light (page 374, section 3.4, lines 2-6) ; and

detecting a wavelength change of the interference light (page 371, section 2.4, lines 14-16 and figure 5).

Regarding claim 52, the optical interference unit of Kawaguchi's device can change the wavelength of the interference light after interaction with the detection target (page 374, section 3.4, lines 2-6).

Regarding claim 53, the optical interference unit is a target detection substrate formed from a film-like material (2) on a substrate (3) which can interact with a detection target, interfere with irradiate light and radiate it as interference light, and can change the wavelength of the interference light after interaction with the detection target (page 374, section 3.4, lines 2-6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, et al. (Kawaguchi, T., Shiro, T., and Iwata, K., "A Device for Visual Detection of Antigens and Antibodies by Means of Light Interference." *Thin Solid Films*. Vol. 91, pp. 369-381 (1990)).

Regarding claim 4, Kawaguchi's wavelength change detecting unit measures a spectrum before wavelength change of the interference light and a spectrum after wavelength change of the interference light, and can measure their differential spectrum (figure 5). The solid line in figure 5 (a, b, c) was taken before the reaction (i.e. before the wavelength change) and the dotted line (a*, b*, c*) in figure 5 was taken after the

reaction (i.e. after the wavelength change). Kawaguchi does not disclose finding a differential spectrum of these two spectra. However, it would be inherent to one of ordinary skill in the art to find a differential spectrum between these two spectra by subtracting their values.

In regards to claim 5, the wavelength change detecting unit of Kawaguchi transforms the spectrum taken before and after the reaction into a spectral intensity (i.e. reflection %) (figure 5). Kawaguchi does not disclose finding a differential spectrum of these two spectra. However, it would be inherent to one of ordinary skill in the art to find a differential spectrum between these two spectra by subtracting their values, and thus, transform this differential spectrum into a spectral intensity.

Regarding claim 6, the wavelength change detecting unit of Kawaguchi is a spectrophotometer (page 372, section 2.4, lines 14-16).

Claims 10, 11, 22-30, 37, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi, et al. (Kawaguchi, T., Shiro, T., and Iwata, K., "A Device for Visual Detection of Antigens and Antibodies by Means of Light Interference." *Thin Solid Films*. Vol. 91, pp. 369-381 (1990)) as applied to claims 1 and 34 above in view of Kinoshita (Kinoshita, T., "Preparation of Structural Color Forming System by Polypeptide-Based LB Films," The Fourth NIMC International Symposium on Photoreaction Control and Photofunctional Materials, pp. 1-9 to 1-12, March 14, 2001).

Regarding claim 10 and 37, Kawaguchi does not disclose the use of rod-shaped material as a film-like material of the apparatus. Kawaguchi does disclose a prior art method for creating a device comprised of a light-reflecting substrate, a light-

interference layer made of Langmuir-Blodgett (LB) films, and an antibody layer to detect antigens and antibodies (page 369, section 1, lines 6-9). The light-interference layer of Kawaguchi's device is the film-like material, as disclosed above. Kinoshita discloses an apparatus that detects interference color forming by orienting rod-like polymers on a substrate using an LB method (page 1-9, section 1, lines 2-6). LB films are created using an LB method. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to create the light-interference layer made of LB films as disclosed by Kawaguchi using an LB method, such as the one disclosed by Kinoshita. This method involves the use of a rod-shaped material in the form of a rod-like polymer.

In regards to claim 11, an LB method involves a coating method, as would be inherent to one of ordinary skill in the art.

Regarding claim 22, Kinoshita discloses the use of a monomolecular layer of a rod-shaped material (rod-like polymers) (page 1-9, section 1, lines 2-6).

In regards to claim 23, the rod-shaped material of Kinoshita is a rod-shaped organic molecule in the form of a rod-shaped organic polymer (page 1-9, section 1, lines 2-6).

Regarding claims 24 and 25, Kinoshita's rod-shaped organic molecule is a helical molecule in the form of an α -helical polypeptide (page 1-9, section 1, lines 2-6).

Regarding claims 26-28, the rod-shaped material of Kinoshita is disclosed as being the model molecules of proteins (page 1-9, section 1, lines 2-6), and thus forms a layer of rod-shaped proteins on a substrate when applied to Kawaguchi's apparatus.

Kawaguchi discloses a device having an immobilized antibody (or antigen) for a protein layer, and when this device is immersed in an aqueous specimen containing antigen (or antibody), an antigen-antibody reaction occurs (page 375, section 3.4, lines 8-12).

Therefore, the rod-shaped material of the proteins must have a target interaction part which can interact with the detection target to create this reaction. The reaction itself is a form of chemical adsorption. Furthermore, the reaction itself involves capturing of a detecting target (antigen or antibody) by the target capturing body (immobilized antigen or antibody in protein layer).

In regards to claim 29, the target capturing body is either an immobilized antibody or an antigen (page 375, section 3.4, lines 8-12).

Regarding claim 30, the antigen and the antibody in claim 29 are included in a group of target capturing bodies that are taken to be functional equivalents of each other. Therefore, the clathrate compound also included in this group and the antigen and antibody of this group are functional equivalents of each other. The antigen and antibody present in Kawaguchi's device are comprised in a monomolecular film, creating a monomolecular host compound (abstract, lines 9-11). The Examiner takes official notice that the monomolecular host compounds listed in claim 30 are well-known monomolecular host compounds in the field of biochemistry. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the monomolecular host compounds of claim 30 with a clathrate compound in a target detection apparatus to detect the presence of antigens and antibodies using color interference, since these compounds are well known and readily available.

In regards to claim 31, Applicant's disclosure mentions that the bonding of the target capturing body to the rod-shaped organic material is not limited. Furthermore, there is disclosed a well-known method of using a protein labeled with avidin and bonding the avidin to a biotin-modified capturing structure. (page 38, all of the first full paragraph) Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use this method in Applicant's apparatus in order to detect interference colors with respect to levels of avidin and biotin interactions.

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawaguchi as applied to claim 1 above, and further in view of Li, et al. (USPN 6,392,756). Kawaguchi does not disclose the use of a laser irradiation device or a device that can irradiate a pencil light beam as the optical radiation unit in the device. Kawaguchi's device measures interference color changes which are responsive to thickness layer increases due to antigen-antibody reactions in the layer (page 375, section 3.4, lines 9-12). Therefore, Kawaguchi's device is taking thickness measurements.

Li discloses a device that determines physical parameters (i.e. thickness) of thin films (layers) deposited on a substrate. Li utilizes a tunable laser source as the optical radiation unit of the thickness measuring device (column 8, lines 43-46). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the tunable laser source of Li with Kawaguchi's device in order to produce stable light in a set wavelength range for detection of the interference colors of the layer. It would have also been obvious to use optics to create a pencil light beam from the

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tunable laser source to create an even more stable light source, resulting in a more accurate measurement.

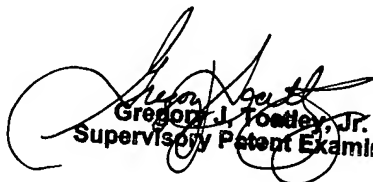
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marissa J. Detschel whose telephone number is 571-272-2716. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on 571-272-2059. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marissa Detschel
December 30, 2005
MJD


Gregory J. Toatley, Jr.
Supervisory Patent Examiner